

REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office action dated November 29, 2006 are respectfully requested.

Applicants petition the Commissioner for a one-month extension of time. A separate petition accompanies this amendment.

I. Amendments

A. Amendments to the specification

The specification is amended to correct obvious typographical errors, for clarity, and for proper grammar.

B. Amendments to the claims

Claims 1 and 20 are amended recite that the introducer is operatively connected to an energy source. Basis for these amendments can be found in claims 33 and 30, respectively. Accordingly, claim 30 is amended to remove reference to the energy source and claim 33 is canceled.

Claim 1 is further amended to correct a grammatical error.

Claim 34 is amended to depend from claim 1.

C. Amendments to the drawings

Applicants propose amendments to Figures 1, 3-5, 6A, 6B, and 7-8 to include elements referenced in the specification.

Applicants propose amendments to Figure 9 for clarity and to correct obvious typographical errors.

Applicants enclose herewith replacement figures 1, 3-6B, and 7-9 labeled "Replacement Sheet."

No new matter is added by way of these amendments.

II. Claim 22

The identifier for claim 22 has been amended in accord with the Examiner's kind suggestion. However, Applicants would like to point out that number 22 was skipped in the numbering of the claims as filed.

III. Rejections under 35 U.S.C. §103

Claims 1-3, 7-9, 11, 12, 15, 18-21, 23, 24, and 30-37 were rejected under 35 U.S.C. §103 as allegedly obvious over LeVeen *et al.* (U.S. Patent No. 5,827,276) in view of Edwards *et al.* (the '675 patent).

Claim 34 was rejected under 35 U.S.C. §103 as allegedly obvious over LeVeen *et al.* and Edwards *et al.* (the '675 patent), and further in view of Edwards *et al.* (U.S. Patent No. 5,507,743, the '743 patent).

A. The Present Claims

Claim 1, as amended, relates to an ablation treatment apparatus including an introducer having a distal portion and a proximal portion, where the introducer is operatively coupled to an energy source.

Claim 20, as amended, relates to a method for creating an ablation volume in a selected tissue mass including providing an ablation device with an introducer being operatively coupled to an energy source and delivering electromagnetic energy from the energy source to the introducer.

B. The Cited References

LEVEEN ET AL. disclose a volumetric ablation apparatus comprising a probe having a plurality of wires deployable from a catheter.

EDWARDS ET AL., THE '675 PATENT relate to a medical probe device for treatment of the hyperplastic tissues of the prostate to treat benign prostatic hyperplasia. The probe comprises a catheter having a stylet guide housing for directing a flexible stylet out of the catheter and into the tissue. The catheter is advanced through ducts adjacent to the

desired treatment area. The stylet is advanced out of the catheter to penetrate the urethral wall and the prostate.

EDWARDS ET AL., THE '743 PATENT issued on April 16, 1996, which is later than the priority date of the present application. Thus, the '743 patent is available as an obviousness reference via 35 U.S.C. 102(e). Effective November 29, 1999, subject matter which was prior art under former 35 U.S.C. 103 via 35 U.S.C. 102(e) is disqualified as prior art against the claimed invention if that subject matter and the claimed invention "were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. The present application and the '743 were, at the time the invention was made, owned by RITA Medical Systems, Inc. as evidenced by Assignments recorded with the USPTO.

C. Analysis

According to the M.P.E.P. § 2143, "to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references (or references when combined) must teach or suggest all the claim limitations."

1. Rejection of claims 1-3, 7-9, 11, 12, 15, 18-21, 23, and 30-37

The combination of LeVeen *et al.* and the '675 patent fails to show or suggest an apparatus having an introducer being operatively coupled to an energy source. LeVeen *et al.* teach an ablation apparatus with a probe that is comprised of a plurality of electrically conductive wires which are bundled at a proximal end and connected to a generator (Col., 7, lines 33-35). The wires are threaded through "an electrically insulated or non-conductive tube or catheter" (Col. 7, lines 36-37). As seen in Fig. 1, this tube or catheter corresponds generally to the introducer of the present claims. Thus, LeVeen *et al.* specifically recite that the introducer/catheter/tube is insulated or

non-conductive. Further, LeVeen *et al.* make no specific mention of coupling the tube/catheter to the energy source.

In the present action, the Examiner states that "LeVeen *et al.* also teach that the introducer may be provided with an electrode (340 – Figure 7 or first set of electrodes 28b in figure 5)" (page 3 of Office action mailed November 29, 2006). Claim 1, as amended, recites that the introducer is coupled to an energy source, which is not the same as being provided with an electrode. A careful review of Fig. 7 and the accompanying description reveals that the tube/catheter is not coupled to an energy source. Rather, element 340 is a collar that may be attached to the exterior of the tube and is electrically connected to the generator by a conductor. The conductor is a separate connection to the generator that is either affixed to the exterior of the tube or threaded through the tube. Again, nowhere is the tube itself connected to the generator. In fact, the presence of a separate conductor connecting the collar to the generator supports Applicants' position. Nowhere do LeVeen *et al.* teach an apparatus where at least one antenna is positioned within and deployed from an active introducer.

Nor does the '675 patent supply the missing teaching. Instead, the '675 patent describes a medical probe device comprising a catheter having a stylet guide housing with one or more stylet ports in a side wall thereof. No mention is made of coupling the catheter to an energy source. Nor would one consider doing so as the device of the '675 patent is introduced through the urethra to a site adjacent the prostate where stylets are advanced from the stylet guide housing. In fact, a major objective for the '675 patent is to not damage the urethra as would happen were the catheter to be coupled to an energy source.

Method claim 20, and the claims dependent thereon, patentably defines over the prior art substantially for the same reasons discussed above. In particular, there is nothing in the teaching of the cited references of delivering electromagnetic energy to an introducer that is operatively coupled to the energy source.

2. Rejection of claim 34

Claim 34 requires that the introducer is coupled to a RF energy source. As noted above, the '743 patent is not available in an obviousness rejection. The deficiencies of the combination of LeVeen *et al.* and the '675 patent are discussed above.

As the references, alone or in combination, fail to teach or suggest all the claim limitations, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 103.

IV. Obviousness-Type Double Patenting Rejection

Claims 1-3, 7-9, 11, 12, 15, 18-24, and 30-37 were rejected under the judicially created doctrine of obviousness-type double patenting as being directed to an invention not patentably distinct from the claims of co-owned U.S. Patent Nos. 5,672,173; 5,672,174; 5,728,143; 5,913,855; 5,928,229; 5,951,547; 5,980,517; 6,080,150; 6,132,425; 6,689,127; 6,958,062; 5,735,847; 5,782,827; and 5,863,290.

A Terminal Disclaimer prepared in accordance with 37 C.F.R. §1.321(b) and (c) was filed on March 12, 2007. The signed Terminal Disclaimer obviates the above obviousness-type double patenting rejections.

Claims 1-3, 7-9, 11, 12, 15, 18-24, and 30-37 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being directed to an invention not patentably distinct from the claims of co-owned U.S. Application No. 11/016,384 in view of the teaching of LeVeen *et al.*

Applicants respectfully request these rejections be held in abeyance until such time as allowable claims are found in this or the '384 application.

CONCLUSION

In view of the foregoing, Applicants submit that the claims pending in the application are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

No further fees are believed due, however, the Commissioner is hereby authorized and requested to charge any deficiency in fees herein to Deposit Account No. 50-2207 to facilitate entry and consideration of this Amendment.

The Examiner is invited to contact Applicants' representative at (650) 838-4410 if it is believed that prosecution of this application may be assisted thereby.

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Respectfully submitted,
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